

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

MDL 2804

THIS DOCUMENT RELATES TO:

Case No. 1:17-md-2804

Track Three Cases

Judge Dan Aaron Polster

Track Three Cases

)

Track Three Cases)
) **OPINION AND ORDER GRANTING IN**
) **PART DEFENDANTS' MOTION TO**
) **EXCLUDE OPINIONS OF CARMEN**
) **CATIZONE**

Before the Court is Defendants' Motion to Exclude the Opinions and Testimony of Carmen Catizone. Plaintiffs filed a response, and Defendants filed a reply. For the reasons stated below, the Motion is **GRANTED IN PART**.

Carmen Catizone offers opinions based on his extensive experience in the practice and regulation of pharmacy. He has undergraduate and masters' degrees in the field of pharmacy from the University of Illinois at Chicago and practiced as a registered pharmacist for over 20 years. For 22 years, Catizone also served as Executive Director of the National Association of Boards of Pharmacy ("NABP"), which works to develop, implement, and enforce uniform standards for its members, including the boards of pharmacy of all 50 states. In that capacity, Catizone focused on "governmental and private entities responsible for regulating pharmacists, technicians, pharmacies, wholesale distributors, and other entities in the pharmaceutical supply chain." Among other initiatives, NABP participated with healthcare and pharmacy associations and pharmaceutical businesses in creating a "consensus document" highlighting the "challenges and

‘red flag’ warning signs related to prescribing and dispensing controlled substance prescriptions.”

Catizone Supplemental Opinion, May 19, 2021 (“Catizone Rpt.”) at 4-7, 34.

Catizone has testified as an expert witness in numerous federal and state court proceedings and DEA enforcement actions, served as liaison to the FDA and DEA, and participated in hundreds of presentations regarding pharmacy issues. Catizone Rpt., Ex. A. His testimony has never been excluded by a court (Catizone Dep. Tr. 130:3-5) and his work has earned many professional honors and awards. Catizone Rpt. at 5.¹

In these *Track Three* cases, Catizone provides opinions concerning Defendants’ conduct with respect to: “maintaining effective policies and practices to guard against the diversion of prescription opioids, their failure to maintain and adhere to well-established pharmacy standards of care, and their dispensing of opioids into Lake and Trumbull Counties despite obvious and significant red flags.” *Id.* at 3.

Relying on numerous authoritative sources, Catizone identified a set of “red flag” warning signals pharmacies could use to identify potentially illegitimate prescriptions. Craig McCann, a data expert, then applied the criteria for each red flag to the DEA Automation of Reports and Consolidation Orders System (“ARCOS”) data to determine the number of “red-flagged” opioid prescriptions dispensed by each of Defendants’ pharmacies in the *Track Three* Counties. *Id.* at 32-52.

The presence of a red flag, Catizone explains, raises a responsibility on the part of both pharmacies and pharmacists to “determine if a prescription is valid and issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his

¹ Catizone has received an Honorary Doctor of Pharmacy from the State of Oklahoma; the Certificate of Appreciation from the District of Columbia; two Food and Drug Administration (FDA) Commissioner Special Citations; the University of Illinois Alumnus of the Year; American Druggist Magazine Pharmacist of the Year; and the University of Illinois, College of Pharmacy, Alumni Association’s Sister Margaret Wright Graduate Award. Catizone Rpt. at 5.

professional practice” – a responsibility that, Catizone opines, Defendants failed to fulfill. *Id.* at 25-27.² According to Catizone, effective steps to address a red flag warning must include: (1) investigating the prescription; and (2) documenting either a resolution of the red flag or a refusal to fill the prescription. *Id.* at 59-62.

I. Legal Standards.

The Court incorporates by reference the applicable *Daubert* legal standards set forth in its *Track One Order Denying Motion to Exclude Rosenthal* (Doc. #: 2495 at 1-10).³

II. Catizone’s Opinions.

Catizone’s Report summarizes his key opinions as follows:

Defendants’ local stores filled thousands of prescriptions presenting red flags without evidence of resolving those red flags.

Defendants and their pharmacists have a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice.

² Catizone explains: “A primary tenet of the standard of care in the practice of pharmacy is a pharmacist’s independent responsibility to ensure that all prescriptions are issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.” Catizone Rpt. at 25. The regulations under the Controlled Substances Act provide:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a).

³ *In re Nat'l Prescription Opiate Litig.* 2019 WL 3934597, at *1-*5 (N.D. Ohio Aug. 20, 2019) (Doc. #: 2495 at 1-10).

* * *

Defendants failed to provide their pharmacists with data, information and the tools necessary to assist their pharmacists in fulfilling their corresponding responsibility duties, including but not limited to, utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion as well [as] to recognize and resolve red flags. The subsequent result of the failure to provide such data, information, and tools was the diversion of significant quantities of controlled substances, particularly opioids, outside of the closed distribution and dispensing system for controlled substances.

Catizone Rpt. at 4.

III. Analysis.

Defendants seek to exclude or limit Catizone's testimony on three grounds. First, they contend his "red flag" metrics for identifying potentially suspicious prescriptions are unreliable and untested. Second, Defendants argue the Court should bar Catizone from testifying that flagged prescriptions were not written for a legitimate medical purpose. Third, Defendants claim Catizone is not qualified and lacks a reliable basis to express opinions regarding any statistical link or correlation between flagged prescriptions and diversion. The Court addresses each argument below.

A. Reliability of Methodology to Identify "Red Flag" Prescriptions.

Catizone identifies certain "red flags" that pharmacies could use to identify potentially suspicious prescriptions. For example, if a "[p]atient was dispensed opioid prescriptions written by at least 3 different prescribers such that all the opioid prescriptions were written in a 45-day period," those prescriptions are suspicious because they present indicia of doctor-shopping to obtain illicit opioids. *See* docket no. 3719-1 at 2 (reciting Catizone's "red flag" no. 3). Similarly, if a "[p]atient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day

and all the prescriptions were written by the same prescriber,” those prescriptions are suspicious because the combination of those three drugs suggests likely abuse.¹ *See id.* at 4 (reciting Catizone’s “red flag” no. 6). Catizone opines that the presence of a “red flag” is a warning signal that pharmacies and pharmacists must investigate to determine if the prescription is, in fact, valid and issued for a legitimate medical purpose.

Defendants argue Catizone’s flagging methodology is unreliable because it is applied “mechanistically” and draws “bright line tests,” regardless of context or other information about the prescription or prescriber. Motion at 3-4; Reply at 1-4. Defendants further object that Catizone has not tested whether his methodology, in fact, accurately flags illegitimate prescriptions. Motion at 4; Reply at 3-4.

As an example of “the arbitrary and irrational nature” of Catizone’s methodology, Defendants point to his designation of a patient traveling more than 25 miles to see her prescriber as a “red flag” metric (suggesting possible pharmacy shopping to obtain illicit opioids). Defendants observe that Catizone admitted in his deposition that 25 miles is not a uniform standard of care requirement and other pharmacists might reasonably determine that 20 miles or 30 miles is an appropriate “red flag” metric. Motion at 3; Reply at 1-3. That other pharmacists might apply differing “red flag” metrics, however, in no way suggests Catizone’s choice of 25 miles is “arbitrary” or “irrational.” As discussed, Catizone identifies “red flags” that pharmacists *could*

¹ The three drugs together are known colloquially as the “Holy Trinity” or the “Houston Cocktail.” *See Pharmacy Times, The Perfect Storm: Opioid Risks and ‘The Holy Trinity,’* <http://bit.ly/HolyTrinityMDL> (“‘The Holy Trinity’ is a drug regimen that includes at least [one] opioid, a benzodiazepine, and carisoprodol. This combination has been rising in popularity and is commonly prescribed by ‘pill mills.’”); Superior HealthPlan, *Deadly Drug Combination: The Houston Cocktail,* <http://bit.ly/HoustonCocktailMDL> (“The Houston Cocktail, also known as the Holy Trinity, is made up of a combination of hydrocodone, alprazolam [a benzodiazepine], and carisoprodol that, when taken together, can be lethal for patients. The combination of these medications do not show clinical benefits and may be viewed as drug-seeking behavior.”).

use to identify potentially suspicious prescriptions. He does not contend that pharmacists *must* use his exact “red flag” metrics, or that pharmacists could not reasonably come up with differing metrics to effectively flag potentially illegitimate prescriptions. As Defendants point out, Catizone testified “pharmacists could properly use their professional and independent judgment to apply different [standard of care] tests.” Reply at 2. Indeed, simple common sense suggests it is reasonable for a pharmacist to be at least a little suspicious about a patient who seeks to fill an opioid prescription at a pharmacy distant from her home, and the further the patient travels to fill an opioid prescription the brighter the “red flag” becomes.

The Court notes Catizone’s methodology is, at the *dispensing* level, analogous to the methodology applied by expert James Rafalski, at the *distribution* level. Rafalski identified seven threshold methods that Defendants *could* use to identify potentially suspicious orders from their retail chain pharmacies – which McCann then applied to various transactional data to identify the number of orders placed by Defendants’ pharmacies that each threshold method would have flagged as potentially suspicious.⁴ Like Catizone, Rafalski did not opine Defendants were *required* to use *his* specific threshold criteria, and Rafalski did not test his threshold methods to determine whether they did, in fact, flag orders that were actually suspicious. The Court in *Track One* nevertheless concluded Rafalski’s methodology was reliable. *See Rafalski T1 Daubert Order, In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934490, at *5-6 (N.D. Ohio Aug. 20, 2019) (Doc. #: 2494 at 11-12). Further, the Court found that, in determining whether Defendants employed effective measures to identify, investigate, and stop shipment of suspicious

⁴ Rafalski further expressed opinions regarding alleged deficiencies in Defendants’ suspicious order monitoring systems (SOMS) and due diligence efforts. *See Rafalski T3 Daubert Order, In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2021 WL 4060359, *1 (Sept. 7, 2021) (Doc. #: 3929 at 1-2).

orders, “it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged.” *Id.*⁵

Here, Catizone’s extensive experience in the practice and regulation of pharmacy provides a reliable basis for him to testify regarding different “red flag” metrics that are *available* to pharmacists to flag potentially illegitimate prescriptions. *See, e.g., First Tenn. Bank Nat’l Ass’n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (where non-scientific expert testimony is involved, the relevant reliability concerns may focus on personal knowledge or experience) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 1450 (1999)). Catizone’s Report cites to various sources supporting his “red flag” criteria, including Defendants’ own policies and DEA and court opinions. *See* Catizone Rpt. at 30-54. The Court has carefully reviewed the relevant portions of Catizone’s Report and finds that his sources, coupled with his extensive relevant experience in pharmacy practice and regulation, create a reliable foundation for *each* of his red flags. *See, e.g., McGuire T1 Daubert Order, In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4254608, at *7 (N.D. Ohio Sept. 9, 2019) (Doc. #: 2577) (allowing expert testimony where the report provided “outside, neutral, authoritative sources showing the bases for [the expert’s] methodology”). Catizone does not testify his particular “red flag” choices are mandatory, and it is factually incorrect and inappropriate to label any of them as arbitrary or irrational.

As with Rafalski, the Court finds that, in determining whether Defendants employed effective measures to investigate and resolve “red flag” warning signs, it would be helpful to the finder of fact to hear evidence about the number of potentially suspicious prescriptions that Catizone’s metrics would have flagged, and the different “red flag” metrics that a pharmacy could

⁵ Similarly, the Court denied Defendants’ motion to exclude Rafalski’s opinions in *Track Three*. *See Rafalski T3 Daubert Order, In re Opiate*, 2021 WL 4060359 (Doc. #: 3929).

choose to employ. *See Rafalski T1 Daubert Order, In re Opiate*, 2019 WL 3934490, at *6 (Doc. #: 2494 at 12). Accordingly, the Court concludes Catizone’s “red-flagging” methodology is reliable and would aid the jury’s determination of material issues in the case. The Court therefore denies Defendants’ motion to exclude Catizone’s opinions on this ground.

B. Opinion that Flagged Prescriptions Were Illegitimate.

Defendants assert Catizone lacks a reliable basis to opine that prescriptions flagged by his methodology were, in fact, not written for a legitimate medical purpose. Motion at 1, 4-5; Reply at 4. As Defendants point out, Catizone agreed in deposition that, if a prescription meets one of his “red-flag” designations, this does not *necessarily* mean the prescription was written for an illegitimate purpose.⁶ *Id.* Defendants ask the Court to clarify that, at trial, Catizone may not testify – and Plaintiffs may not argue – that prescriptions flagged by his methodology were not written for a legitimate medical purpose. *Id.*

Plaintiffs do not respond directly to Defendants’ arguments. Rather, Plaintiffs assert Catizone does not intend to testify about *specific, individual prescriptions* that were not written for a legitimate medical purpose. Response at 11. But Defendants do not ask the Court to limit Catizone’s testimony regarding *specific* prescriptions. Instead, Defendants assert Catizone has not established a sufficient foundation to opine that his flagging methodology, in fact, identifies illegitimate prescriptions. Reply at 4. In other words, Defendants seek to preclude testimony that,

⁶ In deposition, Catizone testified that, absent any documentation such as physician or pharmacist notes regarding the patient or the prescription, he was unable to identify which, or how many flagged prescriptions were written for illegitimate purposes and could only assume “there was a red flag and it was not resolved.” Catizone Dep. Tr. at 160:7-15.

because a prescription is “red-flagged,” it *has to be the case* that it was not written for a legitimate medical purpose.

Plaintiffs explain that Catizone intends to opine that Defendants’ systematic dispensing of “red-flagged” prescriptions, *in the aggregate*, led to increased dispensing of illegitimate prescriptions. Response at 13. Plaintiffs further state: “It is sufficient for Mr. Catizone to make conclusions about the consequences of the sheer magnitude of ‘red flag’ prescriptions *overall*.” *Id.* at 14 (emphasis in original). Again, this argument does not directly address Defendants’ assertion that Catizone should be precluded from opining that “red-flagged” prescriptions were *definitely* not written for a legitimate medical purpose, or even that *some* of them *must* not have been.

The Court concludes Plaintiffs have not shown Catizone is sufficiently qualified to express opinions regarding *actual* consequences – as opposed to *likely* consequences – of Defendants’ alleged conduct, even in the aggregate. On this record, the Court will preclude Catizone from opining that “red-flagged” prescriptions were not written for a legitimate medical purpose. While Catizone’s methodology reliably supports his opinions that “red-flagged” prescriptions were *potentially* illegitimate, Catizone may not opine that the mere presence of a red flag, without more, in fact means a prescription is illegitimate.

C. Opinions Regarding Actual Diversion Caused by Defendants’ Dispensing of “Red-Flagged” Opioid Prescriptions.

Similarly, Defendants argue Catizone is not qualified and lacks a reliable basis to opine that Defendants’ dispensing of “red-flagged” opioid prescriptions, in fact, caused actual diversion. More specifically, Defendants ask the Court to exclude Catizone’s opinions that: (1) a “statistical link” exists between flagged prescriptions and the rate of opioid diversion; and (2) “opioids

dispensed pursuant to flagged prescriptions were diverted at a higher rate than other [prescription] opioids [that were not flagged].” Motion at 6; Reply at 5-6.

In support of their motion, Defendants do not cite or discuss any particular opinions set out in Catizone’s Report.⁷ Rather, Defendants point to Catizone’s deposition testimony that a “significant number of [the prescriptions identified by his red flags] were not for legitimate purposes and were diverted.” Motion at 4-7; Reply at 4-6 (quoting Catizone Dep. Tr. at 174:20-22).⁸ Defendants contend Catizone is not qualified to state this opinion and seek to preclude him from testifying about any “statistical link” or correlation between the number of “red-flagged” prescriptions and the rate of opioid diversion in the *Track Three* Counties. Motion at 6-7; Reply at 5-6.

In response, Plaintiffs assert Catizone’s specialized experience and knowledge in the practice and regulation of pharmacy provide a sufficient foundation for him to testify about “the *likely* public health consequences of the sheer magnitude of Defendants’ disregard of controlled substance laws.” Response at 14-16 (emphasis added). Plaintiffs further state: “The heart of his work at NABP included identifying when opioid dispensing or distribution practices were *likely* to harm the public.” *Id.* at 16 (emphasis added). But Plaintiffs point to no statistical studies Catizone undertook or reviewed showing quantitative links between red-flagged prescriptions and diversion.

⁷ As noted, Catizone’s Report states Defendants’ failure to provide their pharmacists with necessary data, information, and tools to recognize and resolve red flags caused “the diversion of significant quantities” of opioids. Catizone Rpt. at 4.

⁸ In deposition, Catizone testified a “significant” number – which he estimated to be 70-90 percent – of flagged prescriptions were diverted in the *Track Three* Counties. When asked to identify the factors that led him to this conclusion, Catizone stated, “absent patient notes and other documentation, I couldn’t qualify or quantify what significant meant.” Catizone Dep. Tr. at 420: 3-15. He further explained that his review of data showing an increase of opioid prescriptions and drug overdose death rates in the *Track Three* Counties led him “to believe a significant number of those prescriptions were not for legitimate purposes and were diverted.” *Id.* at 174:3-22.

On the other side of the coin, in reply, Defendants do not address Plaintiffs' contention that Catizone is qualified to testify about the *likely* consequences of their alleged conduct. Instead, Defendants double down on their arguments that Catizone lacks the requisite qualifications and a reliable basis to opine that a "significant number" of "red-flagged" prescriptions were diverted.

The record amply demonstrates Catizone has specialized experience and expertise to reliably state how, in his opinion, Defendants' pharmacy practices, procedures, and standards of care resulted in systematic failures to guard against diversion. *See* Catizone Rpt. at 4-7. Further, as Plaintiffs assert (and Defendants do not refute), this expertise also qualifies him to express opinions regarding the *likely* consequences of Defendants' alleged conduct – that is, that dispensing "red flag" prescriptions without conducting adequate investigation or due diligence is likely to lead to diversion. However, Catizone is neither a statistician nor an epidemiologist. The fact that he may be qualified to testify as to *likely* consequences (e.g., that the Defendants' dispensing practices created a greater likelihood that prescriptions were diverted) does not show he has the requisite expertise to opine that Defendants' conduct, in fact, definitely resulted in diversion (or a "significant" or specific amount of diversion) of opioids.

On this record, Plaintiffs have not shown Catizone is qualified to offer expert opinions regarding a statistical link or causal correlation between the number of "red-flagged" prescriptions and actual diversion of opioids, or that "red-flagged" prescriptions, *in fact*, were diverted at a higher rate than other prescription opioids.⁹ *See Decker v. GE Healthcare Inc.*, 770 F.3d 378, 391

⁹ Plaintiffs' argument that other courts have allowed expert testimony regarding red flags is unavailing. *See* Response at 12. The cases they cite do not address the admissibility or reliability of expert causation opinions, but rather, the sufficiency of criminal trial evidence that included, *inter alia*, expert testimony that red flags should have alerted the defendants that prescriptions they dispensed were illegitimate. *See, e.g., United States v. Iriele*, 977 F.3d 1155, 1170 (11th Cir. 2020) (experts in criminal conspiracy case testified at trial that certain drug combinations raised red flags); *United States v. Otuonye*, 995 F.3d 1191, 1211 (10th Cir. 2021) (expert witnesses testified at trial that red flags should have alerted pharmacist that prescriptions were illegitimate).

(6th Cir. 2014) (the proponent of expert testimony must establish the requisite *Daubert* factors by a “preponderance of proof”) (further citations omitted). Catizone may, however, express opinions regarding the *likely* consequences of Defendants’ alleged conduct.

IV. Conclusion.

For the reasons stated above, Defendants’ Motion to Exclude the Opinions and Testimony of Carmen Catizone is **GRANTED IN PART**. Catizone may not offer expert opinions regarding a statistical link or causal correlation between the number of red-flagged prescriptions and the actual diversion of opioids, or that a significant amount (or any number) of prescriptions identified by his “red flag” algorithms were, in fact, definitely illegitimate or actually diverted. Defendants’ Motion to Exclude the Opinions and Testimony of Carmen Catizone is otherwise **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster September 13, 2021

DAN AARON POLSTER

UNITED STATES DISTRICT JUDGE